MISSOURI COMMISSION ON PATIENT SAFETY
MEETING MINUTES
April 7, 2004
10:00 a.m. – 4:00 p.m.
Capitol Plaza Hotel
Jefferson City, Missouri

Official

Commissioners in attendance: Gregg Laiben, Thomas Cartmell, Susan Kendig, Nancy Kimmel, Alan Morris, Kathryn Nelson, Bea Roam, William Schoenhard, Barry Spoon, James Utley, James Buchanan, Stephen Smith, Scott Lakin,

I. CALL TO ORDER
Dr. Gregg Laiben, Chairperson
The meeting was called to order at 10:20 AM. Silent roll call was taken.

Review of Draft Minutes from the previous meeting

There were no corrections noted for the previous draft meeting minutes. Dr. Morris moved to accept. Dr. Buchanan seconded. The minutes were approved on a voice vote and there were no objections.

Housekeeping items:

Handouts were distributed to the subcommittee table.
- In one handout, MDI staff located a report listing the peer review laws of every state.
- Dr. Morris also had an article to distribute.
- MDI staff took some of the draft documents from the last meeting and created sample recommendations. This is distributed as a guideline on format, and to show the general direction of where the Commission seems to be headed.

Two new books from the National Association for State Health Policy are available. Any Commissioner wishing to have their own copy should sign their name on the sheets with each book.

Review of the structure of the final report to the Governor

- Dr. Laiben pointed out that the goal is to produce something that busy legislators will actually have time to read. Therefore, the report should be as short and to-the-point as possible.

    - MDI's report on Medical Malpractice provides a good example for format.
    - There should be a 1 or 2 page summary.
    - Recommendations should be listed on page three and should consist of brief 1 or 2 sentence statements.
- Subcommittees should draft detailed rational and justification for their recommendations. All of the detail may not be included in the final report, but it should definitely be available if needed.
    - There may be a separate supporting document in addition to the final report.
    - The detail provided must support the recommendations being made.
    - The detail needs to be supported by relevant research and studies, but especially by the testimony heard by the Commission.
    - Subcommittees should include reference information in their detail drafts.

Q: Is the format of the Education Subcommittee draft going to be the format used in the final report?
A: As far as supporting detail, the draft is good. However, the report of the actual recommendations may need to be shorter.

II. SUBCOMMITTEES WORKING MORNING

Subcommittees worked independently through the morning. Subcommittee membership: (not all members were present….see attendance)

Patient Safety Center
Dr. Laiben
Kathryn Nelson
William Schoenhard
Scott Lakin

Education for providers and patients
Susan Kendig
Dr. Morris
Dr. Buchanan
Tina Steinman

Protection/peer review
Thomas Cartmell
Kenneth Vuylsteke
Dr. Utley
Dr. Spoon
Kevin Kinkade
Lois Kollmeyer

Data collection and reporting
Dr. Smith

Dr. Jantz
Bea Roam
Lori Scheidt
Nancy Kimmel

Each subcommittee worked at their own table and had access to computers, printers and office supplies. MDI staff was on hand to assist with making copies or running other necessary errands, at the direction of the subcommittees.

The subcommittees stopped for lunch between 12:15 to 1:15 PM.

III. PRESENTATION BY CHILDREN'S MERCY HOSPITAL RISK MANAGEMENT PROFESSIONALS

Sally Surridge, V. P., General Counsel, Cheri Hunt, chief nursing officer, and Dr. Laura Fitzmaurice, clinical Chair for the Department of Pediatrics of Children's Mercy Hospital in KC, provided a presentation and discussion of how Missouri's peer review law impacts their hospital, and how Children's Mercy approaches patient safety. They also provided a copy of the hospital's disclosure policy and sample newsletters. In addition to the information in their handouts, they provided the following information:

- Patient safety efforts at Children's Mercy Hospital in Kansas City (CMH) and satellite campuses in both Missouri and Kansas pre-date by several years the IOM's initial report on safety concerns.
- Safety and quality are tightly connected.
- The main question is how the peer review law impacts CMH's operations. CMH feels it's important to emphasize that patient safety is very important. The presentation may make it appear as though CMH's efforts are focused on protecting itself and evading litigation. This is not at all the case. Therefore, some emphasis is necessary on the patient safety practices in place at CMH.
- Safety and QI teams at CMH include both clinical and non-clinical personnel.
- The medical staff at CMH are also employees. This is an uncommon arrangement.
- CMH and other hospitals are very vested in patient safety. They are very conscious of the clinical and non-clinical participants that affect patient safety.
- The peer review law in Missouri creates 3 broad arenas where the current legal environment impedes or prevents hospitals from taking a systems approach to patient safety. These are reflected in the presentation as the statute itself (problems with definitions and requirements), the attorney-client privilege and where it must be engaged, and the doctrine of work product as a means to protect against litigation.
- The 1999 IOM report on patient safety contains information on each state's legal environment.
- Three main components in Missouri's law are:
    - Who can participate in peer review
        - limited list of clinical professionals, and no non-clinical professionals
        - requires a Missouri license, and excludes recourse to peers licensed in other states

    - How people can participate – Missouri is very specific
        - Appointment is required. This can be cumbersome to get in some cases. It prevents rapid response to urgent situations.
        - Peer review committees are almost never appointed by government or professional bodies, or by health professional corporations.
    - What activities are permitted to be the subject of peer review:
        - Missouri takes a very narrow approach. Activities must relate to the evaluation of care provided by one specific individual to one specific patient.
        - Excludes review (and therefore protection) of trends or QI activities.
- In order to have protection, quality improvement activities must somehow be squeezed into the privilege afforded under the peer review law. This is hard to do and not always desirable.
- As a teaching institution, CMH is especially affected by the fact that students may not participate in peer review activities.
- Many states, including Missouri, fail to protect the evaluation of systems and processes. Again, Missouri's only protection is for evaluation of one professional, one specific incident of care, provided to one patient.

Q: Are you saying CMH doesn't perform systems reviews, or that CMH wants these reviews to be protected from discovery?
A: CMH does perform system reviews, and wishes this information was protected from discovery in a lawsuit. Protection would encourage more reviews in more hospitals.
Q: Have you been sued over these reviews?
A: No, but the fact that it's discoverable means the hospital is taking a risk, just for doing the right thing.
Q: If an attorney attends the reviews, would they be protected under attorney-client privilege?
A: Yes, but an attorney shouldn't have to attend. For review of near-miss situations, it's not cost-effective. An institution shouldn't have to shoehorn their way into protection in this manner. In some institutions, the reviews aren't done at all, because the institution may not be able to afford to have an attorney around, or desire to take the risk of doing it in an attorney's absence.
Q: How often do QI reviews have to get turned over in a lawsuit?
A: Often enough to be troublesome.
Q: Has CMH been forced to turn over results of root cause analysis or failure modes and effects analysis?
A: Not yet. CMH does intensive assessment of events that are critical, but not sentinel. So far, that hasn't been turned over. CMH attributes this in part to their policy on disclosure of information to patients. CMH also shares assessment results freely, because it allows the institution to learn.
Q: So, disclosure mollifies a patient and reduces the urge to sue?
A: In CMH's experience, this is absolutely true.
Q: How do you write legislation that protects the review processes, but punishes providers that ignore the lessons to be learned from those processes?
A: Erosion of protection stifles the movement in the direction of improving patient safety through the methods that are proving to be effective, such as sharing information.

Government agencies should be empowered to monitor this. A central patient safety organization could be an avenue to purge bad actors. Also, the disclosure process exposes bad actors.

- The concern about juries misunderstanding peer review in the context of prior events relates to QI activities. Missouri has a very long statute of limitations. A clinician or hospital could be sued for an event that occurred many years ago. However, the QI activities in place in 2004 could be used to set the standard for this old event. This would be inappropriate.
- Examples from other states are available for designing a system that avoids shoehorning broad patient safety activities into a narrow peer review protection. A good example is a law that allows each institution to decide who will be on a peer review committee.
    - Kansas has a good law for protecting quality improvement activities.
    - Illinois uses the term "medical studies" to protect both care provided to any patient and processes related to safety. Using a term other than "peer review" would help.
- CMH's disclosure policy calls for disclosure to the patient for events that don't rise to the level of sentinel events, in addition to those that do.
    - Initial disclosure comes before root cause analysis activities. Disclosure occurs as soon as the situation is identified and the facts are known.
    - Disclosure involves just a few practitioners and often a social worker.
    - The patient and family must feel supported by the providers. This is the point of disclosure.
    - The hospital's attorney isn't involved in the first visit.

Q: Are doctors uncomfortable agreeing to disclosure? Does the fact that doctors at CMH are employees make this easier for CMH to enforce?
A: The most common problem seems to happen with chronic patients. The question becomes which doctor has the longest relationship with the patient and family. Doctors want to speak out, but get concerned about which doctor is the right doctor to make the disclosure. Doctors at CMH are very protective of residents. In the experience with non-employed physicians, the same issues were noted. So, the fact that CMH's medical staff are employees doesn't seem to change the way doctors feel about disclosure.
Q: Doctors that have to pay their own malpractice premiums seem to fear litigation more, though, don't they?
A: Agree to a point. Even non-employed doctors pick up on the culture. Disclosure reduces claims. It's not privileged information, but it defuses the urge to litigate. Empirical data isn't available, but it's a real phenomenon.

Q: Do you train staff on the disclosure process?
A: Once JCAHO started requiring a formal policy, yes. Before that, no. At this point, because the policy has been around long enough, CMH is doing training on a case-by-case basis, for those that are new to it.

Q: Have you experienced situations where the physician messed up so badly they feel uncomfortable continuing to treat?
A: Yes. Disclosure includes asking the patient or family if they want to continue with this doctor. Doctors and patients are never forced to stay together. Doctors don't like to ask this question, but it's required.

Q: The data and reporting subcommittee, in discussing what to report and in reviewing the event definitions adopted by various institutions, identified three broad categories of "near miss" events. One category is an event that is detected by the organization before any patient is affected in any way. A second category is events that reach patients but have no effect. As far as disclosure and reporting, the third category seems to be a grey area. For events that impact the patient, does CMH require disclosure, even if the impact is temporary and reversible?
A: Any event that that touches the patient is disclosed, whether there is an effect or not. Situations that don't touch the patient are tracked, but not necessarily disclosed. If a near miss could have harmed the patient, intensive assessment is done. Sometimes it's a judgment call as to whether the patient was touched or not. Usually, CMH and the hospital staff start from a presumption there will be disclosure.

Q: Any disclosure would be discoverable. Do you want disclosure to be protected?
A: It's not an issue. Anything that's disclosed would also appear in the medical record, so the hospital isn't doing anything through disclosure that it isn't already at risk for.

Q: With regard to defining a peer review committee more broadly, how do you keep a hospital from just designating the entire hospital staff as the peer review committee?
A: One way might be to define a peer review committee as one for which meeting minutes exist that identify participants.
Q: And non-clinicians should be permitted?
A: Absolutely.

Q: Patient safety goes beyond hospitals. Are the changes you recommend broad enough to get outside the hospital setting?
A: Absolutely. In fact, the changes would make peer review work significantly better in smaller, non-hospital settings.

Q: What additional recommendations do you have for the Commission?
A: **Support disclosure. Also, endorse a system that protects participants in national or regional studies and pilot programs where information sharing is involved. CMH is involved in such a program currently.** Participants are expected to share information that normally an institution wouldn't share out of fear of litigation.

- Missouri's law could promote learning if institutions could anonymously share their experiences with others. If there were a central agency for sharing information, the hospitals could report with identifiers to the agency, and the agency could report to the public in a manner that no particular institution is positively identifiable.
- Risk reduction is not just about one person at one point in time.

Q: Should reports to a central organization be based on actual harm, or on anything that's disclosed to a patient, or what?
A: **The Commission should define what must be reported and allow providers to voluntarily report additional information if they chose.** In other words, sentinel events must be reported, but near-miss data could be left up to each provider. The Center has to have data to be useful. Definitions must be clear.
Q: How should the Center deal with non-reporters?
A: There should be a consequence. Pennsylvania is an example to look at. Failure to report can be penalized if something comes to light through some other means, when it should have been reported.
Q: Reports should be made as they happen, rather than periodically, correct?
A: Yes. Rapid improvements or responses aren't possible with periodic reporting.

Q: How does CMH disclose errors that aren't detected until after a patient is discharged?
A: This happens often. The patient and family are contacted. Patients that traveled far from home to be treated at CMH involve some planning, but discharge doesn't eliminate the disclosure obligation.

Q: When do attorneys get involved with disclosure?
A: Not initially involved. May not be involved at any point. It depends on the situation. If the family brings legal counsel to a disclosure meeting, CMH will too. If any monetary compensation is offered to a patient or family, that's really handled separately from the actual disclosure process, so families are typically advised that legal counsel isn't necessary at these meetings. Medical discussions stay medical. It should be noted that the courts have approval authority over any money paid in a malpractice settlement involving a minor.

The Commission took a short break from 2:30 to 2:50 PM.

IV. BRIEF REPORT FROM EACH SUBCOMMITTEE

Dr. Laiben briefly spoke on how the report will get from subcommittee drafts to a final version.

- MDI staff will put each subcommittee's piece into a unified product. This will take time. There will be three weeks in June during which Commission members will be able to vet the final report. But the report really needs to be done by the end of May.
- The month of April needs to be used to pull the group reports together.
- If possible, the subcommittees should look to have their work finished at the next meeting, and May meetings can be devoted to review and discussion of a complete report.
- There's a possibility that review could be done by email, but all Commission members need to be reasonably satisfied and able to back the final report.
- Each person will not be able to have every concern addressed.

Q: Will there be an opportunity to air any dissenting comments for the record? Consensus may be easier to achieve face-to-face.
A: (Linda Bohrer) If a report were ready by the first meeting in May, this would be the best opportunity to get any dissenting comments on the table.

Q: Who else has to review the report besides the Commissioners?
A: Most of the Commissioners have a formal or informal "constituency" that they are accountable to. So draft reports may need to be circulated to organizations such as the Hospital Association or the professional medical organizations. Buy-in and support from these groups would be a tremendous help.

Linda Bohrer noted that the Education and Patient Safety Center subcommittees are very close to being done. If the other subcommittees need any help, let the MDI staff know what to do.

Protection/peer review:

This committee is working on language for a legislative proposal, and compiling background detail.

- Looking at activities that are already taking place, activities that would be desirable to take place in terms of information exchange, what's currently protected, and what should be protected.
- A lot of discussion around defining "harm" and what must be reported. May borrow heavily from CMH's disclosure and reporting policies.
- The goal is to recommend things that the hospitals won't oppose.
- The proposal may need to have something in it that protects information unless disclosure is ordered pursuant to a government investigation.

Q: Can you write your disclosure generically for broad application outside the hospital setting?
A: Yes.
Q: Has the subcommittee looked at protection for whistleblowers?
A: This was discussed, but felt to be beyond the scope of activity for the Commission. There's a federal regulation in place already, but it apparently applies narrowly to hospital employees and not non-employed medical staff or contractors.

Patient Safety Center:

Few changes from last time.

- One thing to be considered is what a patient safety center should be called. "Patient safety center" may have connotations of regulatory rather than participatory function. The report may contain a name to identify the concept rather than a name as a suggestion.
- The committee is looking at what obligations the center would have to state government. For example, all deaths might need to be reported to the State.

Q: Would reporting to the government be protected or de-identified? If not, this could stifle reporting to the Center.
A: Good comment. This needs to be addressed as well.

Q: What will the center cost?
A: There's no way to determine that in advance. However, the examples from other states provide a range of operating budgets. The committee is going with something like $500,000 to launch and a million dollars annually to operate. There isn't currently a recommendation about funding.

Data collection and reporting:

- Much discussion today involved distinguishing between near misses and sentinel events. The terms "near miss" and "sentinel event" are handy because they are already part of the commonly shared lexicon of patient safety, but they still need to be defined.
- The committee is leaning towards keeping the reporting of near miss situations inside the institution and letting institutions do their own analysis.
- Voluntary reporting of near miss activity could be promoted through various incentives. Examples are protection, feedback, recognition, reduction in medical malpractice premiums, etc.
- The presentation today contained a good set of definitions for defining harm and distinguishing where mandatory reporting would occur.
- The committee does recommend a designated Patient Safety Officer at every institution. This doesn't have to be an FTE. It could be one role played by a person with multiple administrative or clinical functions. The PSO's job would be more than just reporting sentinel events. This person would be involved in the analysis of near miss activity as well.
- Public reporting that isn't useful should be avoided.

Q: Would institutions never have to report to the Boards?
A: Reporting to the Boards wouldn't be affected. The committee is just looking at what should be reported to the Center.

Education:

- There are four basic recommendations. They deal with communication and competence in safety through continuing education. Also, some specific steps that can be taken now are suggested.
- Note, the definition of the term "health care professional". This person may or may not be licensed in Missouri, or licensed at all.

A document will be sent to all Commissioners. **Please read and provide comments.**

Q: You seem to have backed away from mandating continuing medical education on a specific curriculum. Why?

A: Not all professionals require CME. Also, physician organizations in Missouri are likely to oppose any push to require specific, additional CME.
Q: For physicians, CME is state required, not nationally required, correct?
A: Yes, except that board examinations are national.

V. CONCLUDING DISCUSSION

No existing professional, governmental or quasi-governmental body exists that encompasses many different types of providers. No current organization is currently doing the full scope of work proposed to be done by the "Patient Safety Center".

The next meeting will be April 21 at the Capital Plaza Hotel. Tom Cartmell moved to adjourn. The meeting was adjourned at 4:10 PM.